UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,494	10/03/2003	Randall S. Hickle	82021-0044	4564

24633 7590 12/14/2007
HOGAN & HARTSON LLP
IP GROUP, COLUMBIA SQUARE
555 THIRTEENTH STREET, N.W.
WASHINGTON, DC 20004

EXAMINER	
MITCHELL, TEENA KAY	

ART UNIT	PAPER NUMBER
3771	

NOTIFICATION DATE	DELIVERY MODE
12/14/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

dcptopatent@hhlaw.com

MM

Office Action Summary	Application No. 10/677,494	Applicant(s) HICKLE, RANDALL S.	
	Examiner Teena Mitchell	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 9, 13, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickle in view of Jackson (5,513,634).

As to claim 1, Hickle discloses a sedation and analgesia system comprising a patient heath monitor device (12a) adapted so as to be couple to a patient (30) and generate a signal reflecting at least one physiological condition of the patient (55, pg 23, 1st full paragraph); a drug delivery controller (2a) supplying one or more drugs to the patient; a user interface (16); an electronic controller (14) interconnected with the patient health monitor, the user interface and the drug delivery controller, wherein said electronic controller receives said signal and in response to said signal manages the application of the drugs (pg 27, 1st full paragraph).

While Hickle discloses a facemask (30) that couples to the patient, Hickle fails to disclose a bite block. Jackson discloses a bite block (21) comprising a bite portion (at 32) and an opening to access the patient's mouth (23). Jackson further discloses channels (50, 51) that a pair of nasal cannula can be used to directed gas from a source through the channels to the patient's nostrils in order to receive a sedative which would be in fluid communication with said drug delivery controller. It would be reasonable to one of ordinary skill in the art to use the channels via nasal cannula as a viable alternative to a facemask for passing gas to a patient. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the bite block of Arndt with the system of Hickle so that mouth region can be accessed if needed during surgical procedures. Based upon the sedation being delivered through the facemask of Hickle and now substituting the bite block taught by Jackson it would have obvious that the electronic controller of Hickle receives said signal and in response to said signal manages the application of the drugs through the bite block (as the bite block is being substituted for the facemask of Hickle and the drugs were previously delivered through the facemask therefore it would be obvious that the drugs would be delivered through the bite block (i.e., nasal cannula 50, 51) now as one delivery means being substituted for another (i.e., the facemask of Hickle).

As to claim 2, Jackson teaches a bite block that comprises at least one channel (50, 51) extending through said bite portion.

Regarding claim 9, Jackson teaches wherein said nasal cannula comprises both oral delivery chambers to connect to said bite block and nasal delivery chambers (Figs. 1, 2).

As to claim 13, Hickle discloses a sedation and analgesia system, comprising a patient heath monitor device (12a) adapted so as to be couple to a patient (30) and generate a signal reflecting at least one physiological condition of the patient (55, pg 23, 1st full paragraph); a drug delivery controller (2a) supplying one or more drugs to the patient; a user interface (16); a gas monitoring and delivery system (2) supplying one or more types of gas to the patient (paragraph 0081); an electronic controller (14) interconnected with the patient health monitor(12a), the user interface(16), gas monitoring and delivery system (2), and drug delivery controller (2a), wherein said electronic controller receives said signal and in response to said signal manages the application of the drugs (pg 27, 1st full paragraph).

While Hickle discloses a facemask (30) that couples to the patient, Hickle fails to disclose a bite block. Jackson discloses a bite block (21) comprising a bite portion (at 32) and an opening to access the patient's mouth (23; 50, 51; which is at least one channel in fluid communication with said drug delivery controller and said gas monitoring and delivery system because drug is delivered to a user through the bite block of Jackson, one well known delivery means substituted for another). Jackson further discloses channels (50, 51) that a pair of nasal cannula can be used to directed gas from a source through the channels to the nostrils in order to receive a sedative. It would be reasonable to one of ordinary skill in the art to use the channels via nasal cannula as a viable alternative to a facemask for passing gas to a patient. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the bite block of Arndt with the system of Hickle so that mouth region can be accessed if needed during surgical procedures. Inasmuch as anesthesia is delivered via a gas and the device of Jackson is used to deliver a gas, it would have been obvious to one of ordinary skill in the art that a drug could be delivered via the bite block of Jackson.

Claims 3-8, 10, 11, 14-16, 19, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickle in view of Jackson as applied in claims 2 and 13 above and further in view of Kofoed et.al. (6,312,389).

As to claim 3, Hickle and Jackson disclose the system of claim 2. Jackson discloses a channel (50, 51), but fails to mention that a sensor is located in the channel. Kofoed teaches that a sensor (28) located can be located in a channel (40) and have at least one of a sensor (20, 22) and a sampling port (70, 72) connected to a sensor for monitoring gases passing through said at least one channel connected to a nasal cannula for monitoring Carbon dioxide of a patient . It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the bite block of Jackson to employ any well known sensor and sampling port because it would allow a user to monitor the carbon dioxide of a patient.

As to claim 4, Kofoed does further teaches the system wherein said at least one channel is used for at least one or respiratory rate monitoring, oxygen concentration monitoring (carbon dioxide is an oxygen concentration and therefore meets the limitation of the claim), positive and negative respiratory pressure monitoring, temperature monitoring, humidity monitoring, and respiratory flow monitoring.

As to claim 5, Hickle discloses the system wherein said electronic controller alters said drug delivery based on said patient's conditions as monitored by said sensors (page 18, 1st full paragraph).

As to claim 6, Jackson discloses the system wherein said at least one channel of said bite block provides an inlet for gas delivery (at 49).

As to claim 7, Hickle further comprising a gas source (pg 29, 3rd full paragraph) and a gas monitoring and delivery system (2).

As to claim 8, Jackson discloses the system wherein said nasal cannula (40) such that gas from said nasal cannula passes through said channel into said patient's mouth (via openings).

As to claim 10, Hickle/Jackson modified by Kofoed combine to disclose (as presented in claim 3) said at least one channel comprises at least one of a sensor of a sensor and sampling port connected to a sensor for monitoring gas output from said gas supply through said at least one channel. Hickle presents in pg 6 into pg 7 last full paragraph, the system monitors inhaled gases which is from said gas supply.

As to claim 11, Hickle discloses (page 18, 1st full paragraph) said electronic controller alters delivery of gas from said supply based on said patient's conditions as monitored by said sensors.

As to claim 14, Hickle and Jackson disclose the system of claim 13. Jackson discloses a channel (50, 51), but fails to mention that a sensor is located in the channel. Kofoed teaches that a sensor (28) located can be located in a channel(40) and have at least one of a sensor (20, 22) and a sampling port (70, 72) connected to a sensor for monitoring gases passing through said at least one channel. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Kofoed by placing a sensor in the channel of a bite block as disclosed by Hickle/Jackson for monitoring the carbon dioxide of a patient.

As to claim 15, Kofoed does not teach said sensors are wirelessly integrated with said electronic controller however such sensors are well known in the art.

As to claim 16, Hickle discloses (pg 18, 1st full paragraph) said electronic controller alters delivery of gas from said supply based on said patient's conditions as monitored by said sensors.

As to claim 19, Hickle discloses a sedation and analgesia system (2). The bite block of Jackson modified by the teachings of yield a bite block with functionalities that can be integrated with said sedation and analgesia system; Hickle's system provides computer programming capable of comparing patient data and a controller that adjusts the gas delivered to a patient (Hickle pg 16, 1st full paragraph). The method steps would have been obvious because they would have resulted from the use of the device of Hickle/Jackson/Kofoed/Weaver. The bite block of Jackson is fully capable of data being received through the channels of the bite block to the controller of Hickle because there is nothing blocking the flow of data from being transmitted there through.

As to claim 20, Hickle discloses electrical leads (figure 3a, power cord), gas delivery tubes (figure 1, tubes entering facemask), fluid delivery tubes (figure 1, tubes entering face mask). The method steps would have been obvious because they would have resulted from the use of the device of Hickle.

Claims 12 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickle/Jackson as applied to claims 1- above, and further in view of Weaver .

Jackson teaches a bite block however does not teach a tongue depressor. Weaver in a biter block teaches (in figure 3) said bite block that comprises a tongue depressor (exterior tube of 240 in the are of the tongue) extending into the patients mouth, wherein the tongue depressor holds down the patient's tongue and prevents the patient from using their tongue to push out the bit block. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the bite block of Jackson to employ a tongue depressor because it would have provided a means to overlays the tongue of a user and that the bite block would securely restrain the tongue when the patient is placing force on the bite block with their teeth.

Regarding claim 17, note rejection of claim 12 above.

Response to Arguments

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teena Mitchell
Teena Mitchell
Primary Examiner
Art Unit 3771
December 10, 2007

TKM
TKM